

**REMARKS**

Claims 271-273 and 276 are pending. Claims 274 and 275 are withdrawn. Claim 271 has been amended. No new matter has been added. The Applicants expressly reserve the right to prosecute claims drawn to canceled or amended subject matter in subsequent patent applications claiming the benefit of priority to the instant application (35 U.S.C. § 120 and § 121).

For the record, the Applicant notes that the current Office Action incorrectly notes on page 8 that the instant application currently names joint inventors.

**RESPONSE TO CLAIM REJECTIONS UNDER 35 U.S.C. § 112¶1**

Claims 271-273 and 276 are rejected for lacking enablement. Specifically, while the Examiner finds the specification enabled for treating macular degeneration, the Examiner does not find the specification enabled for preventing macular degeneration.

While the Applicant respectfully disagrees, claim 271 has been amended to remove “preventing.” This amendment is being made solely to expedite the prosecution of the instant application. Therefore, as the pending claims no longer recite preventing, the Applicant respectfully requests the withdrawal of the claim rejections made under 35 U.S.C. § 112¶1.

**RESPONSE TO CLAIM REJECTIONS BASED ON 35 USC § 103(a)**

Claims 271-273 and 276 are rejected as being unpatentable over Campochiaro et al. (US Patent No. 6,075,032) in view of Fanjul et al. (*Journal of Biological Chemistry* 1996, 271, 22441-22446). The Applicant respectfully traverses.

To establish a *prima facie* case of obviousness, a number of criteria must be met. For example, all of the limitations of a rejected claim must be taught or suggested in the references relied upon by the Examiner; or they must be among the variations that would have been “obvious to try” to one of ordinary skill in the relevant art in light of the cited references. Moreover, one of ordinary skill in the relevant art must have a reasonable expectation of success

in light of the combination of cited references. Importantly, the reasonable expectation of success must be found in the prior art, and may not be based on the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); see MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

The Applicant notes that there are two types of macular degeneration: "wet" macular degeneration and "dry" macular degeneration. The "wet" form causes vision loss due to abnormal blood vessel growth (i.e., choroidal neovascularization). The "dry" form has a completely different etiology. Vision loss in the "dry" form is caused by a loss of photoreceptor cells (rods and cones) in the central part of the eye which leads to the accumulation of retinotoxic compounds, such as A<sub>2</sub>E, in the cells of the retinal pigment epithelial layer. As disclosed in the instant application (see, for example paragraph [0011] in the summary of the instant applicaiton), it has been found that the production of retinotoxic compounds (such as A<sub>2</sub>E) in discs can be reduced by the administration of a drug that limits the visual cycle. Therefore, in order to more specifically claim certain aspects of the invention which relate to the inhibition of the visual cycle, claim 271 has been amended to require that the ophthalmologic disorder being treated is a disorder characterized by an accumulation of retinotoxic compounds in the cells of the retinal pigment epithelium (e.g., "dry" macular degeneration). Support for this amendment can be found, for example, in paragraph [0530] of the application as filed.

The Applicant respectfully asserts that the cited combination of references fails to teach, suggest or render obvious to try all of the limitations of the pending claims. Specifically, neither Campochiaro nor Fanjul alone or in combination teach treating an ophthalmologic disorder characterized by an accumulation of retinotoxic compounds in the cells of the retinal pigment epithelium with fenretinde. In addition, given that Campochiaro is directed towards treating choroidal neovascularization and Fanjul is directed towards treating cancer, diseases which have completely different etiologies than the ophthalmologic disorders to be treated by the methods of the amended claims, the Applicant respectfully asserts that neither reference renders "obvious to try" treating an ophthalmologic disorder characterized by an accumulation of retinotoxic compounds in the cells of the retinal pigment epithelium with fenretinide. Lastly, the Applicant respectfully asserts that one of skill in the art would not have had a reasonable expectation of success for using compounds of the type identified by Campochiaro for preventing over

proliferation of blood vessels to treat conditions which are not related to such an over proliferation.

Accordingly, the Applicant respectfully requests the withdrawal of the claim rejections under 35 U.S.C. § 103(a) based on Campochiaro in view of Fanjul.

### **FEES**

The Applicant believes that no fees are due in connection with the filing of this Response. Nevertheless, the Commissioner is hereby authorized to charge any and all required fees to our Deposit Account, No. **06-1448**, reference **HMV-091.02**.

### **CONCLUSION**

If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to contact the undersigned.

Date: January 15, 2010

155 Seaport Boulevard  
Boston, MA 02210  
Telephone: (617) 832-1000  
Telecopier: (617) 832-7000

Respectfully submitted,  
FOLEY HOAG LLP

By: /Jacob I. Wasserman/

---

Jacob I. Wasserman, Ph.D.  
Reg. No. 56,929  
Attorney for Applicant